

C. Remarks:

Upon entry of the amendments, claims 1-3, 7, 12, 18 and 61 will be pending in the application. By the amendments herein, Applicants have amended claims 1, 12, and 61, canceled claims 15, 17, and 31-33. Claim 7 has been allowed. Support for the amendment to claim 12 can be found at least in Example 10 of the Specification as filed, *e.g.*, page 71, lines 26-30, and page 74, lines 23-26, and on page 16, lines 8-11. Thus, no new matter has been added. Applicants address the Examiner's arguments *ad seriatim*.

Claim Objections:

Claims 15, 17, and 31-32 were rejected under 37 C.F.R. § 1.75(c) for improper dependency. According to the Examiner, the claims failed to further limit the subject matter of the claim from which they depended.

Applicants have canceled claims 15, 17, and 31-32 herein. Thus, the objections are moot and should be withdrawn.

Rejections under 35 U.S.C. § 112, ¶ 1:

First, claims 12, 15, 17, 31-33, and 61 allegedly fail to meet the written description requirement under 35 U.S.C. § 112, ¶ 1. According to the Examiner, these claims are directed to a genus of molecules for which a complete structure is lacking in the Specification, and for encompassing peptides that differ from SEQ ID NOS: 2 and 18 by reciting conservative amino acid substitutions, D-amino acids, or variant amino acid substitutions thereof. Consequently, the Examiner concludes that because no such molecules have been made, the Specification as filed does not reasonably convey to one skilled in the art that the Applicants had possession of the

claimed invention as of the filing date. *See* Office Action, pages 3-4. Applicants traverse the rejection as applied to the currently pending claims.

Claim 12 has been amended to recite an isolated leptin peptide consisting of an amino acid corresponding to SEQ ID NOS: 2, 8, 10, or 18, wherein said peptide reduces food intake. Support for this claim is found at least on page 16, lines 8-11, and Figure 2 (SEQ ID NOS: 2 and 18), and on page 71, lines 26-30, and page 74, lines 23-26 of the Specification as filed (SEQ ID NOS: 8 and 10). Applicants have provided the sequence of these peptides and have tested them for their ability to modulate body food intake. Thus, the claim meets the written description requirement and the rejection should be withdrawn.

Claim 61 now recites a purified leptin peptide consisting of an amino acid selected from any one of SEQ ID NOS: 2, 8, 10 and 18. For the reasons immediately above, this claim also meets the written description requirement.

Second, claims 1-3, 12, 15, 17-18, 31-33, and 61 allegedly fail to meet the enablement requirement under 35 U.S.C. § 112, ¶ 1. According to the Examiner, the Specification as filed does not reasonably provide enablement for a leptin peptide lacking the amino acid sequences corresponding to SEQ ID NOS: 2 and 18. Consequently, because the claims recite “consisting essentially of” the Examiner concludes that the Specification does not teach how to make or use the invention commensurate in scope with the claims. *See* Office Action, page 4. Applicants traverse the rejection as applied to the claims as amended.

Applicants acknowledge with appreciation the Examiner’s recognition that the Specification is enabling for a leptin peptide consisting of SEQ ID NOS: 2 and 18. Accordingly, claim 1 has been amended to delete SEQ ID NOS: 3-10 and the limitation of less than or equal to

15 amino acid residues, and to include “consisting of” in the transition. Thus, Applicants submit that claim 1 as amended satisfies the enablement requirement.

Similarly, because claims 2-3, and 18 each depend directly from claim 1, and necessarily incorporate all the limitations thereof, these claims stand or fall with claim 1. For the reasons immediately above, claim 1 satisfies the enablement requirement. Accordingly, the enablement rejection of claims 2-3, and 18 should also be withdrawn.

As discussed previously, claim 12 now recites leptin peptides that reduce food intake. As pointed out by Applicants, the Specification sufficiently teaches how to make and use such peptides recited by the claims for the purpose of reducing food intake. There is ample guidance for synthesizing and using these peptides without undue experimentation. *See, e.g.*, Examples 1, 3 and 10. Thus, Applicants submit that claim 12 as amended meets the enablement requirement.

Similarly, claim 61 has been amended to recite “consisting of” in the transition. In view of the above citations to the Examples pertaining to SEQ ID NOS: 2, 8, 10, and 18, the Specification is enabling to those with skill in the art to which this invention pertains, to make and use the invention of claim 61 commensurate in scope with the claim.

For the foregoing reasons, Applicants respectfully submit that the rejections under 35 U.S.C. § 112, ¶ 1 are overcome. Reconsideration and withdrawal of the rejections is requested.

Rejection under 35 U.S.C. § 112, ¶ 2.

Claims 12, 17, and 61 were rejected as indefinite. According to the Examiner, claims 12 and 61 are vague and indefinite as a result of using “consisting essentially of” in the transition. Consequently, the Examiner concluded that the metes and bounds of the claim cannot be determined.

As amended herein, claims 12 and 61 now recite “consisting of” in the transition. Furthermore, claim 17 has been canceled. Thus, the rejections are moot and should be withdrawn.

Rejections under 35 U.S.C. § 102.

Grasso *et al.*

Claims 1-3, 12, 18, and 61 were rejected under § 102(a/b) as anticipated by Grasso *et al.* (1997) (“Grasso”; C1 on the form PTO-1449). Applicants traverse the rejection as applied to the claims as amended.

As amended herein claim 1 is directed to a leptin peptide consisting of either SEQ ID NO: 2 or 18. Claim 1 defines a low molecular weight, highly potent peptide ranging from positions 116-122 of the full length protein. In contrast, Grasso discloses a leptin peptide from positions 116-130 of the full length protein. Accordingly, because Grasso fails to teach all the limitations of the claimed invention, it cannot anticipate claim 1 as amended. Therefore, the rejection should be withdrawn.

Similarly, since claim 2-3, and 18 each depend directly from claim 1, they stand or fall together. For the above reasons, claim 1 is not anticipated by Grasso. Accordingly, the rejections against claims 2-3, and 18 should also be withdrawn.

Claims 12 and 61 have been amended herein to delete the term “essentially” from the transition. Applicants believe this amendment overcomes the teachings of Grasso, as that reference discloses a leptin peptide from positions 116-130 of the full length protein, and SEQ ID NO: 18 is the human analog from positions 116-122 of the full length human protein. Thus,

since Grasso does not meet the limitations of claim 12 and 61, it cannot anticipate the claimed invention.

Reconsideration and withdrawal of the rejections is respectfully requested.

Al-Barazanji *et al.*

Claims 12 and 61 were rejected under § 102(a) as anticipated by Al-Barazanji *et al.* (WO 97/46585) (“Al-Barazanji”; A1 on the form PTO-1449). Applicants traverse the rejection as applied to the claims as amended.

Claims 12 and 61 have been amended herein to delete the term “essentially” from the transition. Applicants believe this amendment overcomes the teachings of Al-Barazanji, as that reference discloses a leptin peptide from positions 116-149 of the full length human protein. In contrast, claims 12 and 61 define a low molecular weight, highly potent version of a peptide corresponding to SEQ ID NO:18, ranging from positions 116-122 of the full length human protein. Accordingly, because Al-Barazanji fails to teach all the limitations of the claimed invention, it cannot anticipate claims 12 and 61 as amended.

Reconsideration and withdrawal of the rejections is respectfully requested.

Conclusion:

Applicants submit that this paper is fully responsive and that the application is in condition for allowance. Such action is respectfully requested. Should any questions or issues arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

This response is due on or before November 26, 2003. No fee is believed due. However, the Commissioner is hereby authorized to charge payment of any necessary fees that may be

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required in connection with the papers transmitted herewith to Deposit Account No. 50-0311,
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Respectfully submitted,

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